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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/054,713  | 01/22/2002  | Gregory A. Fischer   | IOM-P039CO01        | 3974             |
| 22876   | 7590        | 09/30/2005           | EXAMINER            |                  |
| FACTOR & LAKE, LTD<br>1327 W. WASHINGTON BLVD.<br>SUITE 5G/H<br>CHICAGO, IL 60607 |             |                      | THANH, LOAN H       |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 3763                |                  |

DATE MAILED: 09/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                 |                |
|------------------------------|-----------------|----------------|
| <b>Office Action Summary</b> | Application No. | Applicant(s)   |
|                              | 10/054,713      | FISCHER ET AL. |
| Examiner                     | Art Unit        |                |
| LoAn H. Thanh                | 3763            |                |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 17 December 2004.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 67-78 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 67-78 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on 17 December 2004 is/are: a)  accepted or b)  objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 04/14/03.

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_.

## DETAILED ACTION

### *Specification*

The disclosure is objected to because of the following informalities: It is the Examiner's position that Applicant has evoked sixth paragraph, means-plus-function language to define Applicant's invention. Therefore the Examiner requires the Applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o) to explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, and acts perform the function recited in the claim element. Please note that the MPEP clearly states, "Even if the disclosure implicitly sets forth the structure, materials, or acts corresponding to the means-(or step-) plus-function claim element in compliance with 35 U.S.C. 112, first and second paragraphs, the PTO may still require the applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o)...". (Also see **MPEP 2181** (Rev. 1, Feb.2000)) *Wolfensperger*, 302 F.2d at 955, 133 USPQ at 542. ( i.e. Means for utilizing and means for controllably releasing the fluid and a means for directing released fluid). Appropriate correction is required.

Applicant is required to update the status and patent number of the parent application in the first paragraph of the specification since domestic priority is claimed.

### *Claim Objections*

Claims 67-74 are objected to because of the following informalities: It is the Examiner's position that Applicant has evoked sixth paragraph, means-plus-function language to define Applicant's invention. Therefore the Examiner has objected to the claims for the reasons set forth above in the objection to the specification.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

Claim 67 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The means for utilizing fluid to rupture at least a portion of the at least one seal was not disclosed in the parent application 09/960,833 or in this present application as originally filed. It is further unclear what the structure of this utilizing means encompasses. It is unclear whether this is the same structure which is the pinch/blade that is the means for controllably releasing the fluid. The claims have been interpreted in the broadest sense that has been best understood by the Examiner.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 67-73,75-78 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown (U.S. Patent No. 5,377,874).

Brown discloses a sealed fluid chamber having a cavity which is at least partially defined by at least one seal and capable of holding fluid therein, a means for utilizing the fluid (see figs. 1-13), a means for controllably releasing a liquid (the pressure applied by user or the sphere 18). See abstract, col. 1, lines 9-14, and cols. 4-7. Brown discloses a first and second seal (or a first and second region of attachment) which is at either end of the cavity. Another interpretation of the seal/ region is the inside/internal and the outside/external of the seal. The top and bottom surfaces can be considered the upright position or the flat position of the fluid reservoir. The pinch point is considered to be the internal crimp of the seal in the broadest interpretation.

Claims 67-68,75 are rejected under 35 U.S.C. 102(b) as being anticipated by Higashikawa (USPN 5830193).

Higashikawa discloses a fluid reservoir (see figures 1a-1c) comprising a sealed fluid chamber having a cavity therein and at least one seal 26 ( fig. 1a) , a means for utilizing the fluid to rupture at least a portion of the at least one seal ( see fig. 1b) and a means for controllably releasing the fluid from the cavity ( see fig. 1c).

Claims 67-73, 75-78 are rejected under 35 U.S.C. 102(b) as being anticipated by Ness (U.S. Patent No. 5,377,874).

Ness discloses a sealed fluid chamber having a cavity and means for utilizing (see figs. 1-18), a means for controllably releasing a liquid and a means for directing the fluid. See abstract, cols. 2-5. Ness discloses a first and second seal (or a first and second region of attachment) which is at either end of the cavity. Another interpretation

of the seal/ region is the inside/internal and the outside/external of the seal. Ness discloses a top and bottom surface and a pinch point at the attachment region.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 74 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brown (USPN 5,377,874).

Claim 74 is rejected under 35 U.S.C. 103 as being unpatentable over Brown (U.S. Patent No. 5,377,874) or Ness (U. S. Patent No. 4,258,863).

Brown or Ness discloses the invention substantially as claimed. The device is considered to have the seals concentric since it would share a common axis. However, Brown or Ness does not disclose the reservoir having different geometrical shapes. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the geometrical shapes as is well known in the art. Since the instant disclosure describes the geometrical patterns of the reservoir as being merely preferable and does not describe it as contributing any unexpected result to the medical device it would have been obvious to one of ordinary skill in the art. As such, the claimed different geometrical shapes are merely an engineering choice of design lacking in any criticality, and it would have been *prima facie* obvious to one of ordinary

skill in the art at the time the invention was made to make the effective different shapes/geometries of the reservoir.

See MPEP 2144.04. In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966).

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (571) 272-4966. The examiner can normally be reached on Mon. - Fri. (First Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



LoAn H. Thanh  
Primary Examiner  
Art Unit 3763

LT